administered with or after a meal to a human patient, providing a peak plasma concentration (C_{max}) of metformin from about 52.8% to about 75.1% of the C_{max} provided by an equivalent dose of metformin in an immediate release reference formulation.

24. (Amended) A sustained release pharmaceutical formulation comprising a dose of metformin or a pharmaceutically acceptable salt thereof that exhibits the following dissolution profile when tested in a United States Pharmacopeia (USP) type 2 apparatus at 75 rpm in 900 ml of simulated intestinal fluid (pH 7.5 phosphate buffer) and at 37° C.:
after 2 hours 0-25% of the metformin or salt thereof is released;
after 4 hours 10-45% of the metformin or salt thereof is released;
after 8 hours 30-90% of the metformin or salt thereof is released;
after 12 hours not less than 50% of the metformin or salt thereof is released;
after 16 hours not less than 60% of the metformin or salt thereof is released;
and after 20 hours not less than 70% of the metformin or salt thereof is released.

REMARKS

The undersigned attorney gratefully acknowledges the courtesies extended by Examiner Spear and Examiner Fubara during the personal interview conducted at the United States Patent and Trademark Office on March 21, 2002 wherein agreement was reached as set forth in the Interview Summary.

I. Status of the Claims

Claims 1-20 and 24-29 are pending. Claims 4, 9, and 24 have been amended to recite the definitions for T_{max}, C_{max} and USP at the initial occurrence in the claims, as suggested by the Examiner. Claim 5 has been amended to recite "or a pharmaceutically acceptable salt thereof". Support for amended claim 5 is found, e.g., at page 5, lines 28-31.

The Examiner is directed to the following support in the parent application, U.S. Serial

No. 09/045,330, for pending claims 1-20 and 24-29. Support for independent claim 1 is found, e.g., at page 3, lines 9-15 and the parameters for Example 3 as set forth in Table 1 and Figures 7 and 8; support for independent claim 6 is found, e.g., at page 3, lines 16-19 and page 5, line 29; support for independent claim 8 is found, e.g., at Figures 4-8; support for independent claim 9 is found, e.g., at Table 1, C_{max} ratios of Example 3; support for independent claim 12 is found, e.g., at Table 1, T_{max} ratios of Example 3; support for independent claim 15 is found, e.g., at Table 1, T_{max} ratios of Examples 1 and 2; support for independent claim 18 is found, e.g., at Figures 4-8 by measuring the width of the plasma concentration/time curve at 50% of the maximum height of the curve; support for independent claims 24 and 27 is found, e.g., at page 9, lines 32-38; support for dependent claims 2 and 7 is found, e.g. at 4, lines 7-10; support for dependent claims 3, 11, 14, 17, 20, 25, 28 is found, e.g., at page 4, lines 3-6 and page 16, lines 18-22; support for dependent claims 4, 10, 13, 16, 19, 26, 29 is found, e.g., at page 3, lines 16-19; and support for dependent claim 5 is found, e.g., at page 5, lines 28-31.

II. Rejections Under 35 U.S.C. §102(b); §102(e) and §103(a)

In the Office Action, claims 1-29 were rejected under 35 U.S.C. §102(b) as being anticipated by Physician Desk Reference (PDR) on GLUCOPHAGE; claims 1-29 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,955,106 (Moeckel et al.); and claims 1-29 were rejected under 35 U.S.C. §103(a) as being obvious in view of U.S. Patent No. 6,056,977 (Bhagwat et al.).

These prior art references were discussed during the interview and the Examiner agreed to withdraw the rejections based on these references.

III. Double Patenting

In the Office Action, claims 1-29 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,099,859 and claims 1-15 of U.S. Patent No. 5,837,379. Further, claims 1-19 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being

unpatentable over claims 1-54 of copending Application No. 09/594,637.

During the interview, the Examiner agreed to *(i)* withdraw the obvious-type double patenting rejection based on U.S. Patent No.5,837,379 and agreed to *(ii)* reconsider the obvious-type double patenting rejections over U.S. Patent No. 6,099,859 and copending Application No. 09/594,637 based on the guidelines of double patenting set forth in MPEP § 804 which were discussed during the interview.

With respect *to the claims* of U.S. Patent No. 6,099,859 and copending Application No. 09/594,637, it is respectfully submitted that (as discussed during the interview) the MPEP provides that while terms in a claim can be interpreted by referring to the specification, language from the specification (not found in the claims) cannot be considered for purposes of an obvious-type double patenting analysis. it is respectfully submitted that the claimed pharmacokinetic and pharmacodynamic parameters of the presently claimed invention are not obvious in view of those *claims* and the Examiner is requested to remove these rejections.

IV. Information Disclosure Statement

In the Office Action, the Examiner stated that the Information Disclosure Statement submitted on September 17, 2001 is not available in the application. As requested, the Information Disclosure Statement will be resubmitted to the Examiner by hand delivery.

V. Conclusion

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "**Version With Markings To Show Changes Made**."

It is now believed that the above-referenced rejections and objections have been obviated and it is respectfully requested that the rejections and objections be withdrawn. It is believed that all claims are now in condition for allowance.

According to currently recommended Patent Office policy the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview will advance the

prosecution of this application.

An early and favorable action is earnestly solicited.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 
Robert J. Paradiso
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940

Version With Markings To Show Changes Made

IN THE SPECIFICATION

The paragraph on page 4, lines 1-14 of the specification has been amended as follows:

The dosage form of the present invention can provide therapeutic levels of the antihyperglycemic drug for twelve to twenty-four hour periods and does not exhibit a decrease in bioavailability if taken with food. In fact, a slight increase in the bioavailability of the antihyperglycemic [antihypoglycemic] drug is observed when the controlled release dosage form of the present invention is administered with food. In a preferred embodiment, the dosage form will be administered once a day, ideally with or after a meal and most preferably with or after the evening meal, and provide therapeutic levels of the drug throughout the day with peak plasma levels being obtained between 8-12 hours after administration.

IN THE CLAIMS

Claims 21-23 have been canceled.

The claims have been amended as follows:

4. (Amended) The sustained release pharmaceutical formulation of claim 1 wherein said formulation provides a time to peak plasma concentration (T_{max}) [T_{max}] of the antihyperglycemic drug which occurs at a time from about 8 hours to about 12 hours after administration to said human patient.

5. (Amended) The sustained release pharmaceutical formulation of claim 1 wherein said antihyperglycemic drug is metformin or a pharmaceutically acceptable salt thereof.

9. (Amended) A sustained release pharmaceutical formulation comprising a dose of metformin or a pharmaceutically acceptable salt thereof suitable for once daily dosing, said formulation when administered with or after a meal to a human patient, providing a peak plasma concentration (C_{max}) [C_{max}] of metformin from about 52.8% to about 75.1% of the C_{max} provided by an equivalent dose of metformin in an immediate release reference formulation.

24. (Amended) A sustained release pharmaceutical formulation comprising a dose of metformin or a pharmaceutically acceptable salt thereof that exhibits the following dissolution profile when tested in a United States Pharmacopeia (USP) [USP] type 2 apparatus at 75 rpm in 900 ml of simulated intestinal fluid (pH 7.5 phosphate buffer) and at 37° C.:
after 2 hours 0-25% of the metformin or salt thereof is released;
after 4 hours 10-45% of the metformin or salt thereof is released;
after 8 hours 30-90% of the metformin or salt thereof is released;
after 12 hours not less than 50% of the metformin or salt thereof is released;
after 16 hours not less than 60% of the metformin or salt thereof is released;
and after 20 hours not less than 70% of the metformin or salt thereof is released.